Group Art Unit: 3731

Examiner: Richard R. Shaffer

Atty. Docket No.: 101896-252 (DEP-5319)

REMARKS

The final Office Action dated December 10, 2007 addresses claims 1-7, 10-19, 21-27, 29-33, and 35. Claims 2-5, 13-16, and 25 are withdrawn while claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35 stand rejected. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

Amendments to the Claims

Applicants amend independent claims 1, 12, and 24. In particular, claims 1 and 24 are amended to recite that the opening is defined by the U-shaped receiver member. Claim 12 is amended to recite that the protrusions are defined by the U-shaped receiver member. Support for these amendments can be found throughout the specification and drawings, for example at paragraphs [0023], [0024], and [0025]. No new matter is added.

Claim Rejections Pursuant to 35 U.S.C. § 103 - "Parker / Biedermann"

Claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Application No. 2004/0260284 ("Parker") in view of U.S. Application No. 2004/0049190 ("Biedermann").

Claims 1 and 24

Independent claim 1 recites, in relevant part, a U-shaped receiver member having a distal cavity and a proximal recess. The cavity and the recess include an opening extending therebetween that is *defined by the U-shaped receiver member* and that has a size that prevents passage therethrough of a spinal fixation element seated in the proximal recess. Similarly, independent claim 24 recites a method that includes coupling a spinal fixation element to a U-shaped receiver member having a distal cavity and a proximal recess. The cavity and recess include an opening extending therebetween that is *defined by the U-shaped receiver member* and that has a size that prevents passage of the spinal fixation element therethrough.

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Parker is the primary reference in the obviousness rejection, however the Examiner concedes that Parker lacks the opening of claims 1 and 24 and argues that it would have been obvious to modify Parker to include such an opening using the teachings of Biedermann.

Biedermann, however, is equally deficient because it too lacks an opening defined by a U-shaped receiver member. While it is true that Biedermann discloses a central bore (17), the central bore (17) is defined by a pressure element (13), not by the receiver part (6) as required by claims 1 and 24. *Biedermann* at FIG. 3. Even if one were to combine Parker and Biedermann, there is still no teaching or suggestion of an opening defined by a receiver member. Therefore the combination of references proposed by the Examiner lacks a structural limitation of claims 1 and 24.

In addition, there is nothing in any of the cited references to suggest an advantage to forming the opening in the receiver member itself. In fact, Biedermann chose to do the exact opposite, opting instead to use a separate insert – pressure element (13) – to define the opening. A skilled artisan seeking to apply the teachings of Biedermann to Parker would thus be inclined to simply add the entire separate insert element, not to somehow modify the Parker receiver member to define the opening as claimed.

Furthermore, since Parker is already effective in accomplishing its intended purpose, there would have been no motivation to add an opening to it at all, much less an opening defined by the receiver member. Instead, Parker is specifically designed so that the screw can be implanted into the patient first, followed some time later by the receiver member. Access to the screw's driving interface once the receiver member is applied would therefore be an unnecessary feature, serving only to add cost and manufacturing complexity to an already adequate device.

In sum, each of the references cited by the Examiner lack an express structural limitation of the claims and each are completely devoid of any teaching or suggestion to modify one another. Accordingly, claims 1 and 24 are non-obvious and represent allowable subject matter. Claims 6, 7, 10, 11, 26, 27, and 29-31 are allowable at least because they depend from allowable base claims.

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Claim 12

Independent claim 12 recites a spinal anchoring device that includes a U-shaped receiver member. The U-shaped receiver member has a cavity that freely movably seats the head of a bone-engaging member in a distal portion of the cavity and that is configured to receive a spinal fixation element in a proximal portion of the cavity. The proximal and distal portions of the cavity are spaced apart by opposed protrusions *defined by the U-shaped receiver member*.

Neither Parker nor Biedermann, alone or in combination, teach or even suggest the device of claim 12 because they each lack the claimed receiver member having a cavity with proximal and distal portions spaced apart by opposed protrusions defined by the receiver member. First, in Parker, the head-seating and rod-receiving functions occur in two completely separate cavities, not in portions of a single cavity spaced apart by protrusions as required by claim 12. *Parker* at FIG. 1. Similarly, in Biedermann, there are no protrusions defined by the receiving part (6) that space apart the rod-receiving cavity portion (15) from the head-seating cavity portion (7). *Biedermann* at FIG. 3. Instead, these portions (15, 7) are completely isolated from the receiving part (6) by a pressure element (13). *Id.* Accordingly, each of the references relied upon by the Examiner lack a limitation of the claimed device and therefore claim 12 is non-obvious.

The Examiner asserts in the Advisory Action that the claimed protrusions would necessarily be formed if the Parker receiver member were modified according to Biedermann to include a small passageway. As explained above however, the opening in Biedermann is in a separate insert element, not in the receiver member. Any protrusions formed as a result of incorporating the insert element of Biedermann with Parker would thus be defined by the separate insert element, not by the U-shaped receiver member as required by claim 12.

Accordingly, claim 12 is non-obvious and represents allowable subject matter. Claims 17-19 are allowable at least because they depend from an allowable base claim.

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<u>Claim 32</u>

Independent claim 32 recites a spinal anchoring device that includes a bone screw, a U-

shaped receiver member, a fastening element, and a spinal fixation rod. The U-shaped receiver

member has opposed protrusions that define an opening between a proximal seat for receiving the

spinal fixation rod and a distal seat for receiving at least a portion of the head of the bone screw.

The Examiner argues that it would have been obvious to modify the receiver member of

Parker, based on the teachings of Biedermann, to include opposed protrusions that define an opening

between the proximal and distal seats. As discussed above, however, both Parker and Biedermann

fail to teach or even suggest a receiver member that defines an opening, much less a receiver member

having opposed protrusions that define an opening as required by claim 32.

Accordingly each of the references cited by the Examiner lack an express limitation of claim

32 and therefore claim 32 is non-obvious and represents allowable subject matter. Claims 33 and 35

are allowable at least because they depend from an allowable base claim.

Claim Rejections Pursuant to 35 U.S.C. § 103 – "Parker / Errico"

Claims 1, 6, 7, 10-12, 17-19, 21-24, 26, 27, 29-33, and 35 are rejected pursuant to 35 U.S.C.

§ 103(a) as being obvious over Parker in view of U.S. Patent No. 5,690,630 ("Errico"). Applicants

respectfully disagree.

Claims 1 and 24

As noted above, independent claims 1 and 24 each recite an opening defined by a U-shaped

receiver member. The Examiner acknowledges that Parker, the primary reference in this rejection,

lacks such an opening and relies on Errico to remedy this deficiency.

Errico, however, is likewise deficient because it too is devoid of any opening defined by a U-

shaped receiver member. Instead, the opening (155) disclosed by Errico is defined by a locking

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collar (150) that is completely separate and distinct from the Errico receiving member (200). *Errico* at FIGS. 5 and 6. Both Errico and Parker thus lack an opening defined by a receiver member, as explicitly required by claims 1 and 24.

In addition, as explained in detail above with respect to the rejection based on Parker and Biedermann, there would be no motivation to modify Parker at all, since it is already effective in performing its intended function. Moreover, nothing in Errico suggests the desirability of an opening in the receiver member itself. Instead, Errico chose to include a separate insert element – a locking collar (150) – rather than have the receiver member define the opening as required by claims 1 and 24. One skilled in the art seeking to combine Errico and Parker would therefore simply add the entire locking collar of Errico, not just include an opening in the receiver member itself.

Accordingly, both Parker and Errico lack an express structural limitation of the claims and Errico provides no suggestion or motivation to modify Parker to reach the claimed devices. Claims 1 and 24 are thus non-obvious and represent allowable subject matter. Claims 6, 7, 10, 11, 26, 27, and 29-31 are allowable at least because they depend from allowable base claims.

Claim 12

Independent claim 12 recites a spinal anchoring device that includes a U-shaped receiver member. The U-shaped receiver member has a cavity that freely movably seats the head of a bone-engaging member in a distal portion of the cavity and that is configured to receive a spinal fixation element in a proximal portion of the cavity. The proximal and distal portions of the cavity are spaced apart by opposed protrusions *defined by the U-shaped receiver member*.

The Examiner argues that, while Parker lacks a cavity with proximal and distal portions spaced apart by opposed protrusions defined by the U-shaped receiver member, it would have been obvious to modify Parker to have such a cavity based on the teachings of Errico. This argument is flawed however, because Errico likewise lacks the claimed cavity having proximal and distal portions spaced apart by opposed protrusions defined by the receiver member. To the contrary, in Errico, there are no protrusions that space apart the head-seating cavity portion (158) and the rod-receiving cavity portion (206), much less protrusions defined by the receiver member (200). *Errico*

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at FIGS. 5, 6, and 8. Instead, these portions (158, 206) are separated only by a locking collar (150). *Id.*

Accordingly, each of the references relied upon by the Examiner lack a limitation of the claimed device and therefore claim 12 is non-obvious and represents allowable subject matter.

Claims 17-19 are allowable at least because they depend from an allowable base claim.

Claim 32

As explained above, independent claim 32 recites a *U-shaped receiver member having* opposed protrusions that define an opening between proximal and distal seats. The Examiner argues that it would have been obvious to form an opening in the Parker receiver member, based on the teachings of Errico, to reach the device of claim 32.

Errico however, like Biedermann above, completely lacks the claimed receiver member having opposed protrusions that define an opening. Instead, the opening in Errico is not defined by the receiver member (200) at all, but rather is formed by a locking collar (150). *Errico* at FIGS. 5, 6, and 8. In addition, as shown in FIG. 6 of Errico, there are no protrusions whatsoever between proximal and distal seats in the receiver member, and therefore yet another requirement of claim 32 is missing from Errico. Instead, the only protrusion in the Errico receiver member is an annular lip at the base of a tapered chamber (205). *Errico* at FIG. 6. This lip, however, is located distal to both the proximal and distal seating surfaces (207, 154) of Errico and thus cannot define an opening therebetween as required in claim 32. *Errico* at FIGS. 5 and 6.

Accordingly, both Errico and Parker lack express limitations of claim 32 and therefore claim 32 is non-obvious and represents allowable subject matter. Claims 33 and 35 are allowable at least because they depend from an allowable base claim.

Conclusion

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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